

### **DETAILED ACTION**

In view of the arguments, as discussed in more detail below, in the appeal brief filed on 31 March 2009, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing this Office action.

### ***Interview***

Upon review of the appeal brief filed 31 March 2009, and in consultation with Examiner's Supervisor, it was determined that since claims 17-19 did not stand rejected over Yue, and moreover, since the Lai reference is applicable, as will be discussed below, prosecution would need to be reopened. Moreover, Applicant's argument in the Appeal Brief filed 31 March 2009, at page 7, that the limitations in the claims that the

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fastener "cause" the connecting features to engage with the mating elements do not amount to a product-by-process limitation is persuasive for the reasons advanced by Applicant. Thus, in recognition of the extensive prosecution in the record, Examiner initiated a telephonic interview with Applicant's representative, Lisa Adams, on 11 June 2009, in order to attempt to identify allowable subject matter and place the application in condition for allowance in the most efficient manner possible. In the interview, Examiner proposed incorporating the limitations of claim 17 into the independent claims in order to overcome at least the Yue reference. In addition, Examiner suggested submitting evidence in support of the proposition advanced by Applicant that even if the Lai reference were applied and the device thereof modified to be made from a biocompatible material such as titanium, it would not necessarily be "medical grade" so as to be "biocompatible" as claimed. However, Applicant did not agree to these suggestions and no other amendments to place the application into condition for allowance were identified by either party at that time. In considering the question of whether it would have been obvious to have modified the device of Lai to be made of a material such as titanium that would inherently be capable of being used as an implant, Examiner discovered a new ground of rejection over Lai (5,509,328; of record) in view of Carden (6,284,014).

Examiner continues to encourage Applicant to telephone the Examiner and initiate an interview so that the issues remaining in the case can be resolved in the most efficient manner possible.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 7-9, 13-16, 20, 42 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Yue (6,007,536).

Yue discloses a device comprising a rod, e.g., 1, that can be fixed at an angle with respect to a plate, e.g., 2, by means of a fastening element 4 (see Figs. 1A-1C). The device adjusts in a single plane. The plate includes a female connector having arms that receive a male connector (see Fig. 1B). A bore extends through the male and female connector components to allow rotation about a cylindrical mating element attached to the female connector. The fastening element is mated with the female connector. Both the plate and rod are capable of being implanted and used for spinal applications. Screws pass through the device and are capable of being used in the claimed manner. Either portion 1 and/or 2 could be considered to be either a rod or a plate since both are elongate rigid, flat and generally narrow structures. Both are at least capable of being used to provide a support structure for spinal fixation as they provide a rigid, adjustable, biocompatible structure of a generally appropriate size.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 7, 10, 13-20, 42, 43 and 46-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lai (5,509,328) in view of Carden (6,284,014).

Lai discloses a device comprising a first elongate member 10 having a female connector with opposed arms 13 and a second elongate member 20 having a male connector 40 adapted to mate to the female connector (see Fig 2). The members are adjustably coupled to one another. A fastening element locks the elongate members in a fixed position. The devices are angularly adjustable in a single plane. The opposed arms define a recess for receiving the male connector. The device includes a bore 14 extending through the opposed arms on the female connector and through the male connector, and a central mating element 51, 52 extending through the bore for mating the male and female connectors together. The central mating element comprises a cylindrical member 51. The device rotates about this member when it is in a loosened state. The cylindrical member is fixedly coupled to a portion of the female connector, and the male connector is free to rotate about the cylindrical member when loose. The fastening element is effective to engage the cylindrical member to prevent movement of the male connector relative to the female connector when tightened. The fastening element comprises a slot 43 extending through the male connector such that the male

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connector is in the form of a clamp, and wherein the device further comprises a threaded fastener 44 adapted to engage and mate with the male connector to clamp the cylindrical member within the bore. The female connector and male connector rotate about a central axis extending substantially perpendicular to an axis of the first and second elongate members. The fastening element is adapted to extend into a connector along an axis that is substantially parallel to the plane of adjustability. The diameter of the first and second elongate member appears to be generally the same with the diameter of portion 20 being only slightly larger than that of portion 10. A terminal end of the second elongate member (e.g., the flush surface that mates with portion 32) is at a 90 degree angle to a longitudinal axis of the second elongate member. Lai does not explicitly recite the material from which the device is formed. However, Carden teaches a matrix alloy composition comprising titanium that can advantageously be used in both bicycles and in medical implants in order to provide increased rigidity and strength and decreased weight (see, e.g., col. 1, lines 15-34; col. 4, lines 5-41; and col. 16, lines 15-17). It would have been obvious to have formed the device of Lai from a matrix alloy composition comprising titanium, in order to make the device stronger, more rigid and lighter. The resulting structure would inherently be biocompatible. Moreover, it also would have been obvious to have formed the device of Lai from, e.g., titanium, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. It is noted that titanium is a common material for devices of the type set forth by Lai for its light weight and

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strength and titanium is also a widely recognized biocompatible material for medical implants. Screws 35 and 36 are anchors and are capable of being secured to spinal bone.

### ***Response to Arguments***

Applicant's arguments filed March 2009, with regard to the Yue reference, have been considered but are not fully persuasive.

The adjustment portion 4 causes the male connector (i.e., the blade or rod) to engage the mating element (i.e., the pivot pin). The male connector extends from a distal tip to the body itself, which holds the connector; therefore, there is clearly contact between the two. Moreover, since the adjustment portion lifts or lowers the rod and exerts a torque or moment on the mechanism that acts at the mating element (i.e., pivot pin), it causes the male connector to engage with varying degrees of force acting in varying directions on the mating element. While the language at issue is functional in nature, it has been fully considered and given patentable weight. However, the device of Yue is capable of satisfying the claimed function.

Simply because of its size or intended use, it cannot be concluded that the device of Yue could not be used as a spinal fixation device. The device is biocompatible and it provides rigid and adjustable structural support and is at least capable of being used as a spinal support element. It is noted that the device need only be at least capable of performing the claimed function, it does not need to be an optimal or preferred solution.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-4710 (a detailed message should be left if Examiner is unavailable). If attempts to reach the Examiner by telephone or voicemail are unsuccessful, the examiner's supervisor, Eduardo Robert, can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David Comstock/

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733